UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,133	12/27/2000	Russell Mumper	50229-207	3309

7590 12/18/2002

MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER
DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/18/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/748,133	Applicant(s) MUMPER ET AL.	
	Examiner Robert M DeWitty	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-32 are pending in the instant application. Acknowledgement is made of Applicant's response submitted 9/18/02.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vora et al. (U.S. Pat. No. 5,326,737), further in view of Acharya (U.S. Pat. No. 5,102,666) and Benes et al. (U.S. Pat. No. 5,639,469).

Vora et al. relates to the treatment of mucoutaneous disorders. Amelexanox can be used to treat aphthous ulcers and other mucocutaneous disorders in the form of a gel. The dosage forms should slowly release the drug to minimize swallowing of the drug (col. 2, lines 64-67). Various ingredients such as diluents, adhesives, viscosity builders, plasticizers, emulsifiers, flavoring agents, and sweetening agents. However, Vora does not teach using a swellable polymer, and a pH-sensitive polymer in the formulation.

Acharya teaches controlled release compositions containing polycarbophil-type (aka Noveon) component with water in the presence of an active composition. The compositions may be in the form of gels (col. 1, lines 5-15). The invention also teaches a method of controlled release treatment by use of a polymeric carrier containing an active composition, which is then used to contact an area of skin or mucous membrane

to be treated with the active composition (col. 3, lines 15-25). The composition of the invention can be provided in the form of a three-dimensional structure such as a film, wherein the active composition is contained in a matrix. The water used in the polycarbophil may be mixed with other co-solvents, such as polyethylene glycol or propylene glycol (col. 10, lines 61-65).

Benes et al. teaches delivery of a drug (heprinin anticoagulant) across a mucosal surface. It is taught that drugs delivered across oral mucosa avoid hepatic first-pass inactivation, poor or erratic absorption from the gastro-intestinal tract, inactivation by gastro-intestinal fluids, and other modes of inactivation characteristic of oral drug ingestion (col. 1, lines 15-20). The device of Benes includes means for adhereing to mucosa, such as with mucoadhesives. Preferred mucoadhesives include a polymeric resin and hydrophobic elastomeric component. The polymeric resin comprises at least about 55% of carboxylic acid moieties. The carboxylic acid moieties can be present as neutralized carboxylate salts. It is taught that basic polyamines such as Eudragit is suitable for use in neutralizing a resin (col. 5, line 11-col. 6, line 17). Preferred resins include CARBOPOL (col. 5, lines 66-67).

Motivation to use a resin such as CARBOPOL containing carboxylic acid moieties, such as Eudragit, in a mucoadhesive gel would have arisen because of the benefits of delivering drugs across oral mucosa including avoiding hepatic first-pass inactivation, poor or erratic absorption from gastro-intestinal tract, inactivation by gastro-intestinal fluids and other modes of inactivation characteristics of oral drug ingestion.

Whereas the art does not disclose the use of a pH-sensitive polymer, Eudragit, as disclosed, inherently contains such characteristic.

Response to Arguments

2. Applicant's arguments filed 9/18/02 have been fully considered but they are not persuasive.

Applicant asserts that none of the prior art teach a "film-forming polymer forming a film when applied to skin or mucosal surface..." as contained in the amended claim 1. However, Vora clearly teaches using a gel. As discussed above, Acharya teaches formulations that can be in the form of films, such films being used to contact mucosal or skin surfaces. Lastly Benes teaches the administration of drugs across mucosal surfaces. Applicant is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Because the references relate to gels, films contacting mucosal surfaces, and delivery of drugs across mucosal surfaces, it is the examiner's position that the art meets the limitations of the amended claim 1.

Applicant next asserts that Benes would have to be modified so that Eudragit would be combined in gel composition to form a film upon skin or mucosal surface. It is the examiner's position that this assertion is faulty. Benes is directed toward a drug delivery device comprising a matrix with an active ingredient, and a means for maintaining the matrix in contact with a mucosal surface. The matrix can be a gel.

Means for maintaining the matrix in contact with the mucosal surface include mucoadhesives, such mucoadhesives consisting of polymeric resins which contain carboxylic acid moieties. The carboxylic acid moieties can be present as neutralized carboxylate salts, which are suitably neutralized with Eudragit. Thus, Benes does not require modification as it is specifically drawn to a gel-formed delivery device that can consist of Eudragit.

Regarding Applicant's assertion that the examiner has not shown a reasonable expectation of success due to the required modifications of Benes, as the examiner has shown that modification to Benes is not necessary, ~~there is~~ success would be reasonable to one with ordinary skill in the art.

Thus, the rejection is maintained.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
December 6, 2002

MICHAEL G. HARTLEY
PRIMARY EXAMINER